



DEPARTMENT OF AGRICULTURE

3410-02P

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-10-0083; NOP-10-09PR]

RIN 0581-AD17

National Organic Program (NOP); Sunset Review (2012) for Nutrient Vitamins and Minerals

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address a recommendation submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on April 29, 2011. The recommendation pertains to the 2012 Sunset Review of the listing for nutrient vitamins and minerals on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). As recommended by the NOSB, the proposed rule would continue the exemption (use) for nutrient vitamins and minerals for 5 years after the October 21, 2012 sunset date. In addition, the proposed rule would amend the annotation to correct an inaccurate cross reference to U.S. Food and Drug Administration regulations (FDA). The proposed amendment to the annotation would clarify what synthetic substances are allowed as nutrient vitamins and minerals in organic products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may submit written comments on this proposed rule using the following addresses:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW., Room 2646-So., Ag Stop 0268, Washington, DC 20250.

Instructions: All submissions received must include the docket number AMS-NOP-10-0083; NOP-10-09PR, and/or Regulatory Information Number (RIN) 0581-AD17 for this rulemaking. Comments should:

- Directly relate to issues or questions raised by the proposed rule;
- Clearly indicate if you are for or against the proposed rule or some portion of it and your reason for your position. Include recommended language changes as appropriate; and
- Be supported by relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Commenters may include a copy of articles or other references that support their comments. Only the supporting material relevant to your position will be considered.

All comments received will be posted without change to <http://www.regulations.gov>.

The NOP is specifically seeking comments on:

1. The actual economic impacts of this action on the industry, including any expected mitigation factors that the industry may use to comply with the proposed action. We are most interested in refining the upper limit estimates referenced in the Regulatory Impact Analysis to specify the actual costs and benefits of this proposal. This would include any comments on the proportion of sales for different sectors of the organic

market (i.e. infant formula, baby food, fluid milk, breakfast cereals, and pet food) that will be impacted by this action;

2. The adequacy of the estimated impact of the proposed action on small entities; and
3. The length of the proposed compliance date.

Please submit comments related to these topics using the numbering scheme indicated above.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, 1400 Independence Ave., SW, Room 2646-South Building, Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday, (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background.

The Organic Foods Production Act of 1990 (OFPA), (7 U.S.C. 6501-6522), authorizes the establishment of the National List. The National List identifies synthetic substances that are exempted (allowed) in organic production and nonsynthetic substances that are prohibited in organic crop and livestock production. The National List also identifies nonagricultural nonsynthetic, nonagricultural synthetic and nonorganic agricultural substances that may be used in organic handling. The exemptions and prohibitions granted under the OFPA are required to

be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary has authority under the OFPA to renew such exemptions and prohibitions. If the substances are not reviewed by the NOSB within 5 years of their inclusion on the National List and addressed by the Secretary, then their authorized use or prohibition expires under OFPA's sunset provision.

The exemption for the use of nutrient vitamins and minerals in "organic" and "made with organic (specified ingredients or food group(s))" processed products is scheduled to expire on October 21, 2012. The NOP is taking this action to implement the NOSB recommendation to renew the allowance for nutrient vitamins and minerals through October 21, 2017. The NOP has also determined that, within the current listing for nutrient vitamins and minerals, the cross reference to the FDA's fortification policy for food at 21 CFR 104.20 was not accurate and that a correction to the current listing is necessary. This action would clarify what substances are covered under this exemption, consistent with the intent of the current listing as codified by the NOP final rule (65 FR 80548). This correction would facilitate compliance for organic operations, provide certifying agents greater certainty in assessing compliance and enable consumers to discern what substances may be used in organic foods.

The potential impact of this action, including potential costs that could be incurred, and the alternatives considered are presented as part of the Executive Order 12866 section of this proposed rule. Upon issuance of a final rule on this action, the NOP intends to provide a compliance date of two years from the effective date of the amended listing. Prohibitions on the use of ingredients affected by this action would not be enforced until the compliance date. This timeline is intended to allow time for the NOSB's review of petitions for substances not within the scope of the current listing or amended listing and provides the NOP with an opportunity to initiate rulemaking if the Board recommends that such substances be added to the National List.

In addition, the NOP believes this timeline would provide sufficient time for the organic trade to adjust product formulations based on the Board recommendations and rulemaking or to consider relabeling products.

The Secretary appointed members to the NOSB for the first time in January 1992. The NOSB began holding formal committee meetings in May 1992 and its first full Board meeting in September 1992. The NOSB's initial recommendations were presented to the Secretary on August 1, 1994.

In advance of the Board's November 1995 meeting, two technical advisory panel (TAP) reports, one for "Nutrient Vitamins" and one for "Nutrient Minerals", were prepared. These reports were developed to inform the Board's assessment of nutrient vitamins and minerals in consideration of the evaluation criteria for substances considered for inclusion on the National List as established in section 2119(m) of OFPA. The vitamins identified in the TAP review included: vitamins A, D, E, K C, B6, B12; folic acid; thiamin (B1); riboflavin (B2); and biotin. The minerals identified in the TAP report for nutrient minerals included: calcium; phosphorus; magnesium; sulfur; copper; iodine; iron; manganese; and zinc.¹

During the NOSB's November 1995 meeting, the NOSB finalized two recommendations regarding the addition of nutrient substances to organic food. These recommendations were developed to inform the establishment of the National Organic Program (NOP) regulations, including the National List. The first recommendation supported the addition of nutrient vitamins and minerals to the National List with the following annotation, "Accepted for use in

¹ NOSB, 1995. Nutrient Minerals Technical Advisory Panel Review. NOP website, Petitioned Substances Database, "N", available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067005&acct=nopgeninfo>
NOSB, 1995. Nutrient Vitamins Technical Advisory Panel Review. NOP website, Petitioned Substances Database, "N", available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067006&acct=nopgeninfo>

organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.”² During the deliberations on this recommendation, there was discussion about what was meant by “independent professional organizations” and a clarification was made that this recommendation did not mean that vitamins and minerals should be exempt from the National List process.

The second recommendation entitled “Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Food,” articulated the Board’s preference regarding the use of vitamins, minerals, and/or accessory nutrients.³ It stated, “Upon implementation of the National Organic Program (NOP), the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.” The Board clarified that the term “accessory nutrients” referred to nutrients, “not specifically classified as a vitamin or mineral but found to promote optimal health.” The Board commented that excluding the use of accessory nutrients could limit the potential for organic foods to capitalize on future nutritional findings.

Based on the NOSB’s recommendations, the Agricultural Marketing Service (AMS) published a proposed rule on March 13, 2000 (65 FR 13512).⁴ The rule proposed an allowance for nutrient vitamins and minerals in processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” with the following language: “Nutrient

² NOSB, 1995. Final Minutes of the National Organic Standards Board Full Board Meeting Austin, Texas, October 31 - November 4, 1995, available at:

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057496>

³ NOSB, 1995, Final Recommendation Addendum Number 13, *The Use of Nutrient Supplementation in Organic Foods*, available at:

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=stelprdc5058973>

⁴ The proposed rule published in March 2000, was the second proposed rule for the National Organic Program. The first proposed rule was published on December 16, 1997 (62 FR 65850). The National List section in the 1997 proposed rule contained an exemption for “Nutrient supplements.”

vitamins and minerals in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.” The regulation cited as part of this listing refers to the fortification policy for food under the FDA’s jurisdiction. This policy establishes uniform principles for the rational addition of nutrients to foods. In response to the proposed rule, the NOSB submitted a comment recommending that 21 CFR 104.20 “not be the reference for the allowance of nutrient vitamins and minerals”, but did not provide additional context for this position or propose alternate regulatory references.⁵

On December 21, 2000, AMS published a final rule establishing the National Organic Program (65 FR 80548). The final rule retained the listing for nutrient vitamins and minerals as proposed. In the discussion of comments received, the NOP acknowledged commenters’ suggestions that 21 CFR 104.20 was not adequate and should be accompanied by a reference to 21 CFR 101.9(c)(8) for FDA-regulated foods. In the preamble to the final rule, the NOP stated that such suggestions were not appropriate because 21 CFR 101.9 pertained to the declaration of nutrition information on the label and in labeling of a food rather than provisions for nutritional supplementation (65 FR 80615). However, as discussed below, recent consultation with the FDA clarified that 21 CFR 101.9 does identify essential vitamins and minerals.

In 2006, the NOP received a complaint challenging the use of docosahexaenoic acid (DHA) and arachidonic acid (ARA) derived from algae and microbes, respectively (hereinafter referred to as DHA/ARA single-cell oils), in organic infant formulas.⁶ The review of the complaint also led to questions concerning the use of taurine and nucleotides in organic infant

⁵ NOSB Comments to Proposed Rule 7 CFR part 205 (Docket TMD-00-02-PR); submitted June 12, 2000.

⁶ DHA and ARA are omega-3 and omega-6 fatty acids, respectively, which are naturally present in certain foods. Dietary sources of DHA include: cold water fatty fish, meats, and eggs. Dietary sources of ARA include: meat, poultry and eggs. Humans can convert the omega-3 fatty acid alpha-linolenic acid (ALA) to DHA and the omega-6 fatty acid linoleic acid (LA) to ARA. Natural sources of LA and ALA include: vegetable oils, nuts, seeds and some vegetables. Reference: University of Maryland Medical Center, Omega-3 Fatty Acids. Available online at: <http://www.umm.edu/altmed/articles/omega-3-000316.htm>

formula. In November 2006, the NOP closed the complaint stating, “The NOP determined that accessory nutrients, that are non-agricultural, are allowed in the production of products to be sold, labeled or represented as organic under the NOP; provided, they are used in full compliance with Food and Drug Administration (FDA) rules and regulations. Non-agricultural accessory nutrients are covered under § 205.602(b) Synthetics allowed, of the NOP National List (nutrient vitamins and minerals). . . Nutrients allowed under § 205.605(b) are not limited to the nutrients listed in [21 CFR] § 104.20(d)(3), because [21 CFR] § 104.20(f) provides that nutrients may be added to foods as permitted or required by applicable regulations established elsewhere by FDA; for example, 21 CFR Part 107 Infant Formula. . . In summary, we have determined that if added ingredients such as DHA, ARA, nucleotides and taurine are used in full compliance with FDA rules and regulations, they would comply with the NOP National List as currently written.”

In November 2008, the NOP received an inquiry from a certifying agent regarding the allowance of lutein ester (crystalline lutein), a carotenoid, under the listing for nutrient vitamins and minerals in § 205.605(b). The NOP consulted with the FDA and provided a written response which stated, “The FDA has determined that “Crystalline Lutein” does not fall under current fortification policy. . . The nutrients listed in [21 CFR] § 104.20(d)(3) are those that fall under this policy.” The NOP statement that the “accessory nutrient”, lutein ester, is not allowed under the nutrient vitamin and mineral listing at § 205.605(b) is in conflict with the 2006 NOP complaint closure letter that stated that “accessory nutrients” were allowed under the FDA fortification policy.

On March 26, 2010, the NOP published an Advance Notice of Proposed Rulemaking (ANPR) to announce the pending sunset of substances on the National List and opened the public comment process on whether existing exemptions for specified synthetic and nonsynthetic

substances in organic handling should be continued (75 FR 14500).⁷ The ANPR indicated that the exemption for the use of nutrient vitamins and minerals as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” would expire after October 21, 2012, if the listing was not renewed. The public comment period lasted 60 days. Comments were received from organic handlers, ingredient suppliers and trade associations. Comments received supported the continued listing of nutrient vitamins and minerals in organic handling. The written comments can be retrieved at

<http://www.regulations.gov> by searching for the document ID number: AMS-NOP-09-0074.

The NOP provided the NOSB with these public comments to consider in their future deliberations on the status of nutrient vitamins and minerals in organic products after the 2012 sunset date.

Because of continued confusion in the organic industry about the allowance of certain added ingredients, such as DHA, ARA, taurine, and nucleotides, in organic products, the NOP met with FDA staff from the Office of Nutrition, Labeling and Dietary Supplements in April 2010 for clarification of the scope of 21 CFR 104.20. The FDA explained that “nutrients” as referenced in 21 CFR 104.20(f) is intended to pertain only to those nutrients listed in section 104.20(d)(3) and as specified in the standards of identity (21 CFR parts 130-169) for a food or class of foods. The standards of identity for enriched cereal-flours and related products, for example, require fortification at specified levels with thiamin, riboflavin, niacin, iron and folic acid (21 CFR part 137). The FDA noted that some foods have separate requirements, and are not subject to 21 CFR 104.20, such as infant formula which must comply with the nutrient

⁷ The Sunset 2012 ANPR also pertained to the exemptions for synthetic substances and prohibitions for nonsynthetic substances used in crop and livestock production.

requirements at 21 CFR 107.100. The NOP participated in a follow-up discussion with FDA in February 2011, the details of which are discussed below.

In April 2010, the NOP issued an “Action Memorandum to the Chairman of the National Organic Standards Board” at the NOSB meeting to advise the NOSB about the clarifications provided by FDA.⁸ The memorandum conveyed FDA’s interpretation of the fortification policy, as stated in the above paragraph, and requested that the NOSB reexamine the codified listing for nutrient vitamins and minerals to determine what substances are permitted under its scope as part of the scheduled sunset 2012 review. The NOP specifically asked the NOSB to consider: “Are the “nutrient vitamins and minerals” specified within 21 CFR 104.20 aligned with the 1995 NOSB recommendation? If not, are there substances that should be prohibited or additional substances that should be allowed?” This memo stated that the previous interpretation of 21 CFR 104.20 Nutritional Quality Guidelines for Foods was incorrect. The memo also conveyed the NOP’s plan to issue guidance on nutrient vitamins and minerals that would align with the FDA fortification policy. On March 9, 2011, the NOSB Handling Committee’s Sunset 2012 Proposed Recommendation for nutrient vitamins and minerals was posted for public review and comment.⁹ The NOSB Handling Committee recommended that the listing be renewed as follows:

§ 205.605(b): Nutrient Vitamins and Minerals, restricted to materials required or allowed by law for the purpose of enrichment, supplementation or fortification of foods including infant formula, and materials the use of which is supported by the FDA or the Institute of Medicine of the National Academies.” The NOSB Handling Committee stated that they intended to “restore the

⁸ NOP, 2010, Action Memorandum for the Chairman of the National Organic Standards Board, Scope of Nutrient Vitamins and Minerals in Organic Food, available at

<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5084068&acct=nosb>

⁹ NOSB, 2011, Handling Committee Sunset 2012 Proposed Recommendation Nutrient Vitamins and Minerals, available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5089727&acct=nosb>

1995 NOSB recommendation,” and reasoned that, “Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials.”¹⁰

The NOSB Handling Committee received approximately 2,000 comments on their proposed recommendation to change the annotation for nutrient vitamins and minerals. The majority of comments opposed the NOSB Handling Committee’s proposal. Many commenters voiced concern that the proposal would allow, without NOSB review, any synthetic nutrient additive to be allowed in organic products. These commenters stated that only essential nutrients required by the FDA should be allowed in organic products. A trade organization and an organic nonprofit organization specifically suggested that the Committee instead consider an annotation for nutrient vitamins and minerals that would allow essential vitamins and minerals required by FDA in infant formula and other foods. Some commenters further emphasized that the Committee’s proposal would allow an open ended list of allowed substances. These commenters stated that the proposal was not consistent with the required petition and NOSB review process for the National List and, if passed, would provide for a list of substances that certifying agents would have difficulty verifying for compliance during the organic certification process. These commenters advocated for the NOSB to individually review and approve any synthetic additives not provided for on the National List per the OFPA requirements. Other comments supported the proposal for an allowance for nutrient additives based upon the idea that certain additives

¹⁰ Prior to the April 2011 NOSB meeting, the Board indicated that nutrient vitamins and minerals would be withdrawn from the agenda and postponed until the next meeting in Fall 2011. The NOP voiced concern that delaying a sunset vote on nutrient vitamins and minerals would not allow adequate time to publish proposed and final rules to implement the Board’s recommendation prior to the sunset date of October 21, 2012. In that scenario, the listing for nutrient vitamins and minerals would expire and use of synthetic vitamins and minerals would be prohibited in organic foods. The NOP urged the Board to complete the sunset recommendation at the April 2011 meeting as originally scheduled to allow time for completion of rulemaking and to avoid significant disruption to the organic food industry. The NOSB agreed to retain the nutrient vitamins and minerals sunset recommendation on the April 2011 meeting agenda.

may have health benefits and that, without these additives, consumers may consider organic products nutritionally inferior to conventional products. In response to these comments, the Committee withdrew the proposal prior to the April 26-30, 2011, NOSB meeting.

In April 2011, the FDA provided written responses to the questions posed by NOP concerning whether the FDA recognizes or defines “accessory nutrients” and the scope of nutrients covered under the fortification policy. The letter, dated April 14, 2011, reflects the points of discussion during a February 2011 meeting between NOP and FDA.¹¹ FDA’s responses reiterated and expanded upon the information conveyed during an April 2010 NOSB meeting at which the NOP discussed their understanding of FDA’s fortification policy.

The FDA explained that the fortification policy at 21 CFR 104.20 provides for the rational addition of essential nutrients to food for human consumption and the term, “accessory nutrients,” is not defined or used in the fortification policy. FDA considers only “essential nutrients” to be within the scope of its fortification policy at 21 CFR 104.20. The nutrients which FDA has determined to be essential are enumerated in 21 CFR 101.9(c)(8)(iv) with corresponding Reference Daily Intakes (RDIs), and 21 CFR 101.9(c)(9), which includes protein and potassium and the corresponding Daily Reference Values (DRVs). FDA stated that substances identified by USDA as “accessory nutrients” such as omega-3 and omega-6 fatty acids, inositol, choline, carnitine, and taurine are not essential nutrients listed under 101.9(c)(8)(iv) and are, therefore, not within the scope of FDA’s fortification policy at 21 CFR 104.20. The FDA also clarified that infant formula is not within the scope of the fortification policy; the requirements in 21 CFR part 107 pertain to required and essential nutrients for infant formula and include minimum and maximum amounts for those nutrients.

¹¹ FDA Response to NOP - Questions and Answers Regarding Nutrient Fortification of Foods. April 14, 2011. Available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5090415>

At the April 2011 NOSB meeting, the NOP suggested that the NOSB amend the annotation for nutrient vitamins and minerals to cite the regulatory references, 21 CFR 101.9, 21 CFR 107.10 and 21 CFR 107.100, which identify essential and approved vitamins, minerals and other nutrients for infant formula and fortification of food. The NOP suggested that an annotation change would correct an inaccurate cross reference to FDA fortification policy for food at 21 CFR 104.20 . The NOP further explained that this annotation change would expand the allowance for certain nutrients by providing for the continued use of essential nutrients in organic infant formula; the use of essential nutrients in infant formula is not covered under the existing FDA reference in the NOP regulations. The NOP also stated that the listing for nutrient vitamins and minerals should encompass a clear, discernible list of permitted substances. The proposed change would convey the intent of the codified listing by coherently and accurately stating which synthetic nutrient substances may be added to organic food and organic infant formula.

At the conclusion of the April 2011 meeting, the NOSB approved a recommendation to renew the listing for nutrient vitamins and minerals as presently codified without amendment.¹² The Board signaled its intent to propose an annotation change to the nutrient vitamins and minerals listing at its November 2011 meeting, after considering the information provided by FDA and the numerous public comments addressing this issue. However, since NOP is taking action to amend the listing through this proposed rule, the NOSB has opted to remove proposing a recommendation for an annotation change on nutrient vitamins and minerals from their November 2011 meeting agenda. In addition to the ANPR for Sunset 2012 published on March

¹² NOSB, 2011, Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), Nutrient Vitamins and Minerals Sunset, available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091724>

26, 2010, the NOSB received additional public comment concerning the pending sunset of this listing in response to three Federal Register notices announcing meetings of the NOSB and its planned deliberations on recommendations involving Sunset 2012 substances. The notices were published in the Federal Register as follows: March 17, 2010 (75 FR 12723), September 20, 2010 (75 FR 57194), and March 4, 2011 (76 FR 12013). The NOSB received further written and oral testimony concerning nutrient vitamins and minerals at all three of these public business meetings which occurred in Woodland, CA on April 26 – 29, 2010, in Madison, WI on October 25 – 28, 2010, and in Seattle, WA on April 26 – 29, 2011. The written comments can be retrieved via <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-10-0021 (May 2010 meeting); AMS-NOP-10-0068 (October 2010 meeting); and AMS-NOP-11-05 (April 2011 meeting). The oral comments were recorded in the meeting transcripts available on the NOP Web site, <http://www.ams.usda.gov/nop>.

II. Overview of Proposed Amendments

This proposed rule would amend § 205.605 of the National List regulations by amending paragraph (b) that currently reads: “Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods” to be revised as follows: “Vitamins and minerals. For food—vitamins and minerals identified as essential in 21 CFR § 101.9. For infant formula—vitamins and minerals as required by 21 CFR § 107.100 or § 107.10.”

This proposed change conveys the intent of the codified listing by coherently and accurately stating which synthetic nutrient substances may be added to organic food and organic infant formula. The parameters of the amended listing are based upon FDA’s determination of which vitamins and minerals are essential for human nutrition and required in infant formula which is consistent with the intended purpose of the current listing. Nutrients which are not

considered essential vitamins and minerals, by the FDA (under 21 CFR 101.9(c)(8)(iv)), would be subject to individual evaluation in accordance with the criteria set forth in sections 6517(c) and 6518(m) of OFPA and § 205.600 of the NOP regulations. Petitions for the addition of such substances to the National List need to be submitted in accordance with the Guidelines on Submitting National List Petitions (72 FR 2167).¹³

The NOP regulations as promulgated, contained the listing for “Nutrient vitamins and minerals in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods,” in § 205.605(b) of the National List. In effect, that provision permits the addition of synthetic forms of nutrient vitamins and minerals to processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).” However, the NOP incorrectly interpreted FDA’s fortification policy, codified at 21 CFR 104.20, and allowed substances that are not authorized under the current reference in the NOP regulations.

Two sections, 21 CFR 104.20(d)(3) and (f), have caused confusion and incorrect interpretations of which substances are allowed in organic foods. Section 104.20(d)(3) identifies 21 nutrients (19 vitamins and minerals with a Recommended Dietary Intake (RDI), plus protein and potassium which each have a Dietary Reference Value (DRV)) which may be added to foods in accordance with conditions specified within section 104.20. The FDA fortification policy specifies the circumstances under which these 21 nutrients may be added to food: to correct a dietary insufficiency; restore nutrients to a level representative of the food prior to storage, handling and processing; maintain a balanced nutrient profile; improve the quality or a replacement food; or be added as permitted or required by another FDA regulation. In the

¹³ The Guidelines on Submitting National List Petitions is available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5048809&acct=nopgeninfo>

context of organic production, the fortification policy referenced in the current nutrient vitamins and minerals listing covers only the vitamins and minerals identified in § 104.20(d)(3).

In 2006, the NOP incorrectly interpreted 21 CFR 104.20(f), which states, “Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter.” The NOP interpreted “or required by applicable regulations established elsewhere in this chapter,” as allowing the addition of a broader range of nutrients to organic products than those specified in § 104.20(d)(3). According to this interpretation, the fortification policy for food included the nutrition specifications for infant formula and nutrients for which there is Generally Regarded as Safe (GRAS) notification or the manufacturer’s self-determination of GRAS. The FDA maintains a GRAS Notice Inventory:

<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm>.

Fortification of Foods

To correct the previous interpretation and provide firm guidance to the organic industry, the NOP sought clarification from FDA regarding the scope of nutrients, vitamins and minerals permitted by the fortification policy for addition to foods. The FDA informed the NOP that the fortification policy covers the nutrients identified in (i) 21 CFR 104.20(d)(3), (ii) an additional 6 nutrients that have been determined essential listed in 21 CFR 101.9(c)(8)(iv), and (iii) nutrients as required by other FDA regulations, which include those pertaining to a common or usual name (21 CFR part 102), standard of identity (21 CFR parts 130-169), or nutritional quality guideline (21 CFR 104.47). This contrasts with current practices in certain sectors of the organic industry which have added nutrients to types of organic products, such as infant formula or pet food, which are not covered under the fortification policy. Added ingredients which are

confirmed or self-determined as GRAS, but not designated as essential nutrients by FDA, have also been added to organic products. Examples of ingredients added to organic products which are outside the parameters of FDA's fortification policy include certain forms of DHA and ARA in fluid milk and dairy products, and taurine in pet food.¹⁴

Since the establishment of the fortification policy in 1980, the FDA has designated six other nutrients as “essential” and permitted for fortification in foods. These include Vitamin K, manganese, selenium, chromium, molybdenum and chloride. As indicated in 21 CFR 104.20(a), the list of nutrients in (d)(3) was not expected to remain static: “It is reasonable to anticipate that the Reference Daily Intakes (RDI’s) as delineated in § 101.9 of this chapter and in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change the levels of specific RDI’s as improved knowledge about human nutrient requirements and allowances develops.”

Therefore, the FDA suggested to NOP that a more appropriate reference to capture all of the essential vitamins and minerals that may be permitted for fortification of food, in accordance with the conditions specified in the fortification policy, is 21 CFR 101.9(c)(8)(iv) and potassium (101.9(c)(9)). The NOP is proposing to amend the current listing for nutrient vitamins and minerals to include this reference for fortification of foods. Paragraph (c)(8)(iv) in § 101.9 identifies 25 vitamins and minerals which are essential in human nutrition and their corresponding Reference Daily Intake (RDI) values. Paragraph (c)(9) in § 101.9 includes the listing for potassium and the corresponding Daily Reference Value (DRV). The RDI and

¹⁴ Section 205.606 of the National List identifies two components of fish oil, by Chemical Abstracts Service (CAS) numbers, that are allowed as ingredients in organic products. These are the omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Forms of DHA which do not meet these criteria are not otherwise allowed in organic products as a nutrient vitamin or mineral, regardless of GRAS designation. FDA has not determined that either DHA or ARA are essential nutrients for the fortification of food. Pet food does not fall within the scope of FDA’s fortification policy. The NOP will address nutrient vitamins and minerals in pet food through a separate rulemaking.

potassium DRV values specified in 21 CFR 101.9 are based on the National Academy of Sciences' Recommended Daily Allowance and "Estimated Safe and Adequate Daily Dietary Intakes." The NOP expects that the NOSB will review any FDA updates or additions pertaining to the requirements for essential vitamins and minerals, as codified in 21 CFR 101.9, during future sunset reviews of the vitamins and minerals listing.

Infant Formula

The NOP is also proposing to amend the current listing for nutrient vitamins and minerals by adding the regulatory references that are applicable to the FDA nutrient specifications for infant formula. According to FDA, the fortification policy for food does not apply to infant formula. The FDA developed separate nutrient specifications for infant formula. The NOP allowance for nutrient vitamins and minerals, as codified, references only the fortification policy for food, and, therefore, does not provide for the addition of vitamins and minerals in organic infant formula.

In practice, however, NOP-certified organic infant formulas which comply with the FDA nutrient requirements have been produced for years. This was based upon an interpretation advanced by the NOP that the FDA fortification policy extended to the nutrient specifications for infant formula. Most of the organic infant formulas in the current marketplace contain some added ingredients which are permitted, but not required by FDA, such as, ARA, DHA, nucleotides, taurine, carnitine, lutein and lycopene. This proposed action, incorporating the FDA nutrient requirements for infant formula, would ensure that there is no unintended impediment to the continued formulation of organic infant formula with vitamins and minerals to comply with FDA requirements. This proposed action would also prohibit the use of non-required ingredients added to organic infant formula, such as ARA, DHA, nucleotides, taurine, carnitine, lutein, and

lycopene, unless the NOSB issues recommendations to add any such substances to the National List and such recommendations are codified through rulemaking.

The infant formula nutrient specifications at 21 CFR 107.100 stipulate the required vitamins and minerals and the corresponding minimum and maximum levels at which these may be present in infant formula. Section 21 CFR 107.100 identifies all required vitamins and minerals for infant formula with the exception of selenium, the addition of which is allowed for in 21 CFR 107.10. Paragraph (b)(5) of section 107.10 provides that any additional vitamin or mineral may be declared on the label provided it has been identified as essential by the National Academy of Sciences or FDA and is provided at a level, if known, considered to have biological significance through publications by the National Academy of Sciences or by FDA in the Federal Register. Selenium has been identified as essential by the National Academy of Sciences. The FDA advised that sections 107.100 and 107.10, in combination, would account for all of the vitamins and minerals required in infant formula. The incorporation of section 107.10 will ensure that any vitamins and minerals which are declared essential and added to infant formula in the future will be allowed in organic infant formula. This will enable manufacturers of organic infant formula to apply significant nutritional findings concerning vitamin and mineral requirements without delay. Section 107.100 also requires certain levels of protein, fat and linoleic acid in infant formula. As these nutrients are available from agricultural sources, the NOP expects that these will be provided in organic form.

As a result of this proposed action, the essential vitamins and minerals listed as RDI in 101.9(c)(8)(iv) and potassium listed as DRV (101.9(c)(9)) would be permitted for addition to organic foods; in addition, the vitamins and minerals required by FDA for infant formula, would be permitted for addition to organic infant formula. An essential vitamin or mineral must have a

safe and lawful source, e.g., the substance must be an approved food additive or GRAS under the conditions of the intended use, and there should be no determination by FDA, in regulation or matter of policy, that fortification with that nutrient is inappropriate. To convey that vitamins and minerals are the only types of substances permitted under this categorical allowance, the proposed amendment omits the word “nutrient” because that term encompasses a wider range of substances.

Over the last ten years, the NOP incorrectly allowed a broad allowance of “accessory nutrients” that is not aligned with the codified allowance for nutrient vitamins and minerals in organic products, as confirmed by FDA’s clarification of the scope of the fortification policy. In practice, added ingredients, which are considered GRAS (either via GRAS notification submission or a manufacturer’s self-determination), but are not designated as essential vitamins and minerals per FDA (21 CFR 101.9(c)(8)(iv)), are being added to organic products based upon an incorrect NOP interpretation of FDA fortification policy. The proposed action will clarify which vitamins and minerals are allowed in organic food products, allow organic infant formula to contain essential vitamins and minerals, and ensure the NOSB reviews and approves all substances used in organic production and handling. Moreover, this proposed action does not preclude the potential to add individual exemptions for additional nutrients to the National List. Such substances can be petitioned for inclusion on the National List and would be subject to individual evaluation by the NOSB according to the criteria established in OFPA and the NOP regulations for such purpose.

In effect, this proposed action would permit the following vitamins and minerals in organic foods (in accordance with FDA specifications for use): Vitamins A, C, K, D, E, thiamin, riboflavin, niacin, B6, B12, biotin, folate, pantothenic acid, calcium, iron, phosphorus,

magnesium, zinc, iodine, copper, potassium, selenium, manganese, chromium, molybdenum, and chloride. This proposed action would also permit the following vitamins and minerals in organic infant formula: Vitamins A, C, K, D, E, thiamin, riboflavin, niacin, B6, B12, biotin, folic acid, pantothenic acid, choline, inositol, calcium, iron, phosphorus, magnesium, zinc, iodine, copper, sodium, potassium, selenium, manganese, and chloride. Table 1 compares the vitamins and minerals allowed under the current 21 CFR 104.20 reference and illustrates the complete set of vitamins and minerals that would be permitted in organic food and infant formula per this proposed action.

Table 1. Summary of Regulatory References for Vitamins and Minerals in Organic Food and Organic Infant Formula

Substance	Current Reference for Nutrient Vitamins and Minerals Per 21 CFR § 104.20(d)(3)	Proposed Reference for Vitamins and Minerals	
		Food Essential per 21 CFR § 101.9(c)(8) or § 101.9(c)(9)	Infant formula Required per 21 CFR § 107.100 or § 107.10
Vitamin A	Yes	Yes	Yes
Vitamin C	Yes	Yes	Yes
Calcium	Yes	Yes	Yes
Iron	Yes	Yes	Yes
Vitamin D	Yes	Yes	Yes
Vitamin E	Yes	Yes	Yes
Vitamin K	-	Yes	Yes
Thiamin	Yes	Yes	Yes
Riboflavin	Yes	Yes	Yes

Niacin	Yes	Yes	Yes
Vitamin B6	Yes	Yes	Yes
Folate	Yes	Yes	Yes
Vitamin B12	Yes	Yes	Yes
Biotin	Yes	Yes	Yes*
Pantothenic acid	Yes	Yes	Yes
Choline	-	-	Yes*
Inositol	-	-	Yes*
Phosphorus	Yes	Yes	Yes
Magnesium	Yes	Yes	Yes
Zinc	Yes	Yes	Yes
Iodine	Yes	Yes	Yes
Copper	Yes	Yes	Yes
Sodium	-	-	Yes
Potassium	Yes	Yes	Yes
Selenium	-	Yes	Yes
Manganese	-	Yes	Yes
Chromium	-	Yes	-
Molybdenum	-	Yes	-
Chloride	-	Yes	Yes

* Required only for non-milk based infant formulas.

Table 2 shows examples, but is not an exhaustive list, of ingredients which are used in organic products and would be prohibited from use under this action. This table also indicates

whether a petition to add the substance to the National List has been submitted to the National Organic Standards Board.

Table 2. Examples of Affected Ingredients in Organic Products

Ingredient	Petition submitted to NOSB
Docosahexanoic Acid (DHA) algal oil	Yes
Arachidonic Acid (ARA) single- cell oil	Yes
Taurine (separate petitions for infant formula and pet food)	Yes
Inositol	Yes
Choline (two separate petitions for infant formula and infant food, and all other foods)	Yes
Ascorbyl Palmitate	Yes
Beta-carotene*	Yes
L-carnitine	Submitted to NOP and under revision by petitioner
Lycopene	Yes
Nucleotides	Yes
Lutein	Submitted to NOP and under revision by petitioner
L-Methionine	Yes

*The beta-carotene petition is for the synthetic form. Beta-carotene extract color is currently listed in section 205.606 as a nonorganically produced agricultural ingredient allowed in products labeled “organic” when an organic version is not commercially available.

III. Related Documents

Three notices were published announcing meetings of the NOSB and its planned deliberations on recommendations involving Sunset 2012 substances including nutrient vitamins and minerals. The notices were published in the Federal Register as follows: (1) March 17, 2010 (75 FR 12723); (2) September 20, 2010 (75 FR 57194); and (3) March 4, 2011 (76 FR 12013).

On March 26, 2010, the NOP published an Advance Notice of Proposed Rulemaking (75 FR 14500) to make the public aware that the allowance for synthetic nutrient vitamins and minerals, among other substances, will expire for use in organic handling, if not reviewed by the NOSB and renewed by the Secretary.

IV. Statutory and Regulatory Authority

The OFPA, as amended [7 U.S.C. 6501-6522], authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Section 6518(k) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having a substances evaluated for inclusion on or deletion from the National List. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP website at: <http://www.ams.usda.gov/nop>. The Sunset Provision in section 6517(e) of the OFPA provides that no exemption or prohibition on the National List will remain valid after 5 years unless the exemption or prohibition has been reviewed and the Secretary renews the listing.

A. Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an “economically significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

AMS is specifically seeking comments on the actual economic impacts of this action on the industry, including any expected mitigation factors that the industry may use to comply with the proposed action. We are most interested in refining the upper limit estimates referenced in the Regulatory Impact Analysis to specify the actual costs and benefits of this proposal. The costs and benefits are summarized in Table 3, below, and described in detail in this section. Comments on the proportion of sales for different sectors of the organic market (i.e. infant formula, baby food, fluid milk, breakfast cereals, and pet food) that will be impacted by this action would be pertinent.

Table 3. Summary of costs and benefits

Costs (range)	Benefits
\$500 million - \$4.2 billion The upper limit is the upper limit for sales of product categories that would be impacted by this action.	Establishes a clear, finite list of essential and required vitamins and mineral for use in organic food and infant formula.
	Facilitates the use of essential or required vitamins and minerals in organic food and infant formula
	Fosters certainty in determining whether a specific ingredient can be used in an organic

	product
	Facilitates enforcement of organic product composition standards

Need for the Rule

The National List within the NOP regulations provides for the use of “Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods,” under 7 CFR 205.605(b). The reference to 21 CFR 104.20 is to FDA’s fortification policy. In 2006, the NOP asserted that the scope of the FDA fortification policy provided for the use of a broader range of nutrients than those explicitly listed in those guidelines. The NOP interpretation affected an allowance for “accessory nutrients,” permitting the use of substances which are Generally Recognized As Safe (GRAS), but are neither vitamin or mineral, nor required by regulation. In 2010, the NOP consulted with FDA to clarify the parameters of the fortification policy and confirmed that the NOP interpretation did not align with the intent of the FDA guidelines. The FDA clarified that the fortification policy provides for the use of only essential vitamins and minerals (under 21 CFR 101.9(c)(8)(iv)) plus potassium and protein (21 CFR 101.9 (c)(9)), which is a more prescribed set of substances than permitted under the NOP interpretation of that policy.¹⁵

The NOP’s interpretation facilitated the potential for the use of a wide spectrum of substances, having unique properties and functions. It incorrectly suggested to organic producers and handlers that a number of unspecified substances could qualify for use under the nutrient

¹⁵ Correspondence from Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration to National Organic Program, U.S. Department of Agriculture. April 14, 2011. Available at www.ams.usda.gov/nop

vitamins and minerals exemption and be added to organic products. It also suggests that the exemption provides an allowance for an open list of substances, potentially encompassing dozens of nutrients, the complete inventory of which is difficult for the NOP and consumers to discern. As a result, the existing exemption remains vulnerable to misinterpretation, which undermines the ability of the certifying agents and NOP to make consistent decisions about the use of nutrient substances in organic products. It is imperative to eliminate uncertainty and enable organic operations to make confident business decisions and to demonstrate effective oversight of organic production to maintain consumer trust.

Furthermore, the NOP thought that the fortification policy provided for the addition of nutrients to infant formula. The FDA indicated that this was inaccurate as the nutrient specifications for infant formula, provided at 21 CFR part 107, are separate from the fortification policy at 21 CFR 104.20. Absent this reference to 21 CFR part 107, the NOP regulations do not correctly provide for the formulation of infant formula that would meet FDA requirements. Therefore, this action is also necessary to incorporate the correct FDA citation with respect to the addition of required vitamins and minerals to organic infant formula.

The NOP and NOSB have provided four opportunities for public comment on this issue and the total number of comments submitted exceeds two thousand.¹⁶ Public comment surged in response to the NOSB April 2011 meeting notice which announced that the NOSB Handling Committee would present a recommendation for nutrient vitamins and minerals. The NOSB Handling Committee recommended that the listing be renewed as follows: “§ 205.605(b): Nutrient Vitamins and Minerals, restricted to materials required or allowed by law for the

¹⁶ An Advanced Notice of Proposed Rulemaking (ANPR) announcing the pending sunset of the nutrient vitamins and minerals listing was published in the Federal Register on March 26, 2010 (75 FR 14500) and requested comments. Three NOSB meeting notices also provided opportunity for public comment on this issue. The notices were published in the Federal Register as follows: March 17, 2010 (75 FR 12723), September 20, 2010 (75 FR 57194), and March 4, 2011 (76 FR 12013).

purpose of enrichment, supplementation or fortification of foods including infant formula, and materials the use of which is supported by the FDA or the Institute of Medicine of the National Academies.” As described earlier, the majority of comments opposed the NOSB Handling Committee’s proposal. Some expressed the preference for a complete prohibition on nutrient additives in organic products, while others advocated for the review of each individual nonagricultural substance for inclusion on the National List. This proposed rule is responsive to numerous public comments advocating for a clearly defined exemption.

Regulatory Objective

The primary purpose of this proposed action is to clarify and accurately provide for the parameters of the exemption for the use of nutrient vitamins and minerals in organic products in accordance with FDA regulatory provisions. The FDA fortification policy is referenced in the current listing to establish parameters for what nutrient vitamins and minerals may be used in organic handling. The proposed rule would correct the regulatory references to clearly delineate that only essential vitamins and minerals are permitted in organic foods under this exemption. This proposed action would correctly identify FDA required vitamins and minerals that may be added to organic infant formula. Other synthetic substances that are not specifically referenced by the proposed exemption would be prohibited from use in organic products unless there is an explicit National List exemption for such use.

This action would clarify for certifying agents, organic operations, consumers, and other interested persons which vitamins and minerals are permitted for use in organic products. It would also ensure that other nutrient substances are subject to the thorough and public review that is accorded all substances petitioned for addition to the National List.

Alternatives Considered

Alternatives to this proposed rulemaking that were considered include: (1) Renew the existing listing for nutrient vitamins and minerals; or (2) in lieu of a rule, issue guidance stating NOP's intent to interpret the current listing for nutrient vitamins and minerals as proposed in this action.

The first alternative considered was to renew the listing for "Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods," without change would extend the National List exemption for the use of nutrient vitamins and minerals until the next sunset date of October 21, 2017. The current listing contains an inaccurate reference to FDA's fortification policy for food, the scope of which the NOP erroneously interpreted to be broader than intended by the original NOSB 1995 recommendations on the nutrient fortification of foods. This option would leave in place a regulatory provision that remains vulnerable to misinterpretation regarding what substances are permitted in organic products. Failing to take action could perpetuate business decisions that are based on an inaccurate reading of the fortification policy resulting in the use of various ingredients which are not explicitly provided for on the National List. The continued use of synthetic ingredients which do not appear on the National List, whether by renewing the current listing or grandfathering in the affected substances, is not a plausible option because this is inconsistent with the Organic Foods Production Act of 1990. The statute prohibits the Secretary from allowing synthetic substances in the National List other than those proposed by the National Organic Standards Board (7 U.S.C. 6517(d)(2)). Only the NOSB has the authority to recommend adding a synthetic substance to the National List and grandfathering in these substances would bypass the NOSB review process which is mandated in order for such substances to be used in organic handling. In addition, pursuing this alternative runs counter to the prevailing

public support, as expressed through comments to the Sunset 2012 ANPR and the NOSB meeting notices, for NOP action to precisely clarify the permitted nutrient vitamins and minerals in organic handling.

Furthermore, the NOP is now cognizant that the FDA fortification policy does not cover infant formula. Infant formula is comprised of agricultural products and falls within the scope of NOP certification. It has developed into a robust organic product category and recorded a 2.3 percent growth in sales in 2010.¹⁷ The NOP believes that it is imperative to confirm the eligibility of infant formula for organic certification by accurately providing for the use of vitamins and minerals to meet FDA requirements for infant formula. Therefore, the NOP did not believe this alternative was appropriate.

The second alternative considered would result in the issuance of guidance, rather than a regulatory change. Upon receiving FDA clarification on the fortification policy, the NOP considered conveying which nutrient vitamins and minerals would be permitted in organic processed food through guidance. However, upon further review, the NOP believes that this route would not adequately address the issue of correcting the incomplete and inaccurate FDA references in the regulatory annotations as well as the resultant overly broad NOP interpretations. The NOP believes that correcting the inaccuracies in the regulation is preferable and the appropriate course of action to bring certainty to the vitamins and mineral area of organic food production.

Baseline

Based on USDA data from the Economic Research Service (ERS), the total acreage of certified organic land grew from 1.8 million acres in 2000 to 4.8 million acres in 2008, of which

¹⁷ Organic Trade Association, 2011. *2011 Organic Industry Survey*. Brattleboro, VT.

approximately 2.2 million acres was pasture and rangeland.¹⁸ The number of certified organic producers in the U.S. nearly doubled in that time period rising from approximately 7,000 in 2000 to nearly 13,000 in 2008.¹⁹

The increasing production capacity for organic agricultural products parallels growth trends in sales of organic products. Since implementation of the NOP, the organic industry has experienced consecutive years of growth demonstrated by increasing sales to consumers. In 2010, U.S. retail sales of organic food and beverages totaled \$26.7 billion.²⁰ The pace of double-digit sales growth that persisted from 2002-2008 has dipped, but the 7.7 percent growth recorded from 2009-2010, marked an increase from the previous year. The top grossing organic food categories in terms of sales for 2010 are fruits and vegetables (39.7%), dairy (14.6%) and packaged/prepared foods, which includes baby formula and baby food (13.9%). Sales of dry breakfast goods, which includes cereals, grew 3.0% in the year 2010, exceeding \$1 million. Organic frozen prepared foods account for the highest sales within the packaged/prepared foods category. According to the Organic Trade Association's Organic Industry Survey 2011, the most often cited barrier to growth in this category, is rising commodity costs.²¹

The year-to-year increases in sales of organic foods coincides with changes in marketing, as organic products have become increasingly available through conventional marketing channels, in addition to natural product retailers. In 2006, nearly equal shares of organic products were sold in conventional venues and natural product outlets and by 2010, the balance

¹⁸ U.S. Department of Agriculture, Economic Research Service. 2008. *U.S. Organic Agriculture, 1992-2008*, data set, available at www.ers.usda.gov/data/organicERS

¹⁹ Ibid.

²⁰ Organic Trade Association, 2011.

²¹ Ibid.

shifted to mass-market groceries which sold 54 percent of organic food.²² There is also evidence of a shift in consumer purchasing patterns, expanding beyond the traditional consumption of organic fruits and vegetables to other organic products, such as dairy, beverages, packaged foods, and breads and grains.²³ After fruits and vegetables, the organic food categories which experienced the greatest sales growth in 2010 were dairy, condiments, snack foods, and breads and grains.²⁴

This Regulatory Impact Analysis (RIA) focuses on five product categories in which the NOP believes the impact of the proposed rule will be concentrated: infant formula; baby food; milk; breakfast cereal; and pet food. The NOP used the Organic Trade Association's April 2011 White Paper on the Fortification of Organic Foods to identify several product categories that would likely be impacted by regulatory action with respect to the listing for nutrient vitamins and minerals.²⁵ A fuller description of current fortification in these products is provided in the discussion of costs below. Table 4 provides an overview of the recent market statistics for these product categories.

Table 4. 2010 Organic Sales and Growth Rates for Select Organic Products

Category	2010 Sales	2010 Growth
Infant Formula ^a	\$695 million	1.9%
Baby Food ^a	\$296 million	2.3%
Milk/cream ^a	\$2.14 billion	10.2%
Dry Breakfast Goods ^{a*}	\$1 billion	3.0%
Pet Food ^b	\$116 million	18.4%

²² Dimitri, Carolyn, and Lydia Oberholtzer. *Marketing U.S. Organic Foods: Recent Trends From Farms to Consumers*. Economic Information Bulletin No. 58. U.S. Dept. of Agriculture, Economic Research Service. September 2009.

²³ Ibid.

²⁴ Organic Trade Association, 2011.

²⁵ Organic Trade Association, 2011. *Fortification of Organic Foods, OTA Task Force White Paper*.

Total	\$4.2 billion	

^aFigures obtained from Organic Trade Association, “2011 Organic Industry Survey”.

^bFigures obtained from Sundale Research, 2011. “State of the Industry: Natural and Organic Pet Food in the U.S., 4th Edition”, Bayshore, N.Y.

*For the purposes of this proposed action, the NOP used “dry breakfast goods” as a synonym for breakfast cereal.

Benefits to the Proposed Rule

The current regulatory provisions present challenges to certifying agents and organic operations in complying with and enforcing regulations regarding the use of nutrient vitamins and minerals. In April 2010, the NOP informed certifying agents of the corrected interpretation of the FDA fortification policy and the impact on the exemption for nutrient vitamins and minerals.²⁶ This proposed correction provides certifying agents with a more clear direction for future certification decisions concerning vitamins, minerals and other substances in organic product formulations. Further, this proposed action also would ensure that exemptions for the use of vitamins, minerals and other nutrients are subject to NOSB evaluation in accordance with the criteria established in 7 U.S.C. 6518(m). Finally, the proposed amendment also would correct the regulation with regard to infant formula under the NOP. Organic infant formula has been marketed since the implementation of the NOP regulations in 2002. The current NOP regulations, however, do not specifically provide a correct reference for the use of vitamins and minerals required by FDA in organic infant formula.

This proposed action would facilitate the use of any additional vitamins or minerals that the FDA may determine to be required or essential for human nutrition. The FDA regulatory citations, 21 CFR 101.9, 107.100 and 107.10, that would replace the current reference to 21 CFR 104.20, contain lists of vitamins and minerals for food and infant formula. The lists within these

²⁶ NOP, 2010, Action Memorandum for the Chairman of the National Organic Standards Board, Scope of Nutrient Vitamins and Minerals in Organic Food, available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5084068&acct=nosb>

sections are updated as warranted to incorporate additional nutrients which FDA has designated as essential or required. For example, since the implementation of the fortification policy in 1980, the FDA has modified the list of essential nutrients to include vitamin K, manganese, selenium, chromium, molybdenum and chloride. By including the proposed references to 21 CFR 101.9, 107.100 and 107.10, any essential or required vitamins and minerals which are added to those regulations would also be allowed for use in organic food and infant formula. During the sunset review of the proposed listing for vitamins and minerals, the NOSB would review any updates to the vitamins and minerals listed in those sections.

Costs of Proposed Rule

This action would impact any certified organic operation which adds substances to organic products that are not essential vitamins and minerals for human nutrition, as enumerated in 21 CFR 101.9, or required vitamins and minerals for infant formula, as enumerated in 21 CFR 107.100 and 107.10. Based on information provided in the OTA White Paper on the Fortification of Organic Foods, the impacts would be concentrated within 5 categories of organic products discussed herein in which nutrient supplementation has been more prevalent: infant formula, baby food, milk, breakfast cereal, and pet food. In aggregate, we anticipate that the upper limit for sales of the organic product categories affected by this proposed action would be \$4.1 billion. We emphasize that this is an estimated upper limit that reflects the total sales of the 5 categories of organic products. Because AMS believes that only a subset of these sales would be impacted by this action, the actual costs of mitigation to comply with the regulatory change are expected to be significantly lower than the total sales value. However, the AMS does not have sufficient data to estimate these costs and is therefore seeking public comment to further analyze the costs of the final rule. OTA provided a conservative estimate that the economic

impact of fortified organic product sales is in the range of \$500 million annually. However, it is not possible for AMS to evaluate the accuracy of this estimate due to the use of proprietary data and lack of information of what assumptions were used to determine this economic impact.

The following discussion explains the basis for AMS's estimate by product category, any underlying assumptions and potential mitigating factors.

Infant Formula. Organic handlers which are not in compliance with this proposed rule would be required to reformulate or relabel their products or exit the organic infant formula market.²⁷ According to measurements by the USDA Economic Research Service, 99.5 percent of organic infant formula contained DHA/ARA as of the first quarter in 2009.²⁸ The NOP assumes that the percentage of organic infant formula containing DHA algal oil and ARA single-cell oil has not fluctuated and for the purposes of this analysis, that essentially all organic infant formula contains DHA algal oil and ARA single-cell oil. The OTA reported that sales of organic infant formula were \$689 million in 2010. Therefore, we anticipate that the entire \$689 million organic infant formula industry would be impacted by this proposed action.

AMS believes the estimate impact of this proposed action on organic infant formula may be inflated for several reasons. At the April 2011 NOSB meeting, the NOP informed the organic industry that the prior NOP interpretation of the listing for nutrient vitamins and minerals was incorrect. The NOP indicated its intent to implement the fortification policy, referenced in the codified listing as 21 CFR 104.20, in accordance with FDA's interpretation of that policy. The NOP also advised that other substances could be petitioned for addition to the National List.

²⁷ According to NOP research, it appears that there are 5 major entities which offer organic infant formula exclusively with DHA algal oil and ARA single-cell oil. Three of the five also market nonorganic infant formulas; therefore, the impact of this action to each entity could be buffered by sustained business related to the nonorganic formulas. Data from ERS which shows that organic infant formulas have a minimal share, 0.8 percent, of the total infant formula market supports the prediction of a more limited impact on the entities which offer both organic and nonorganic formulas.

²⁸ ERS determined this number from Nielsen Scantrack data which contains weekly sales information from a sample of over 14,000 U.S. grocery stores.

Since that announcement, six petitions have been submitted for substances that are added to organic infant formula, but are not required by FDA. As of the publication of this proposed action, petitions for the following substances have been submitted to the NOP: DHA algal oil, ARA single-cell oil, taurine, choline, inositol, ascorbyl palmitate, beta-carotene, L-carnitine, lycopene, nucleotides, lutein and L-methionine. The NOSB will consider the petitions for DHA algal oil and ARA single-cell oil at the November 29 - December 2, 2011 meeting. .

AMS proposes a two year implementation phase before this rule becomes effective. AMS believes that the NOP's advance disclosure of its intent with respect to nutrient vitamins and minerals, in combination with a proposed two year implementation phase, will minimize disruption to the organic industry. The length of time is calculated to provide time for the NOSB to conclude its recommendations on petitions for substances impacted by this rule and to complete any rulemaking necessitated by NOSB recommendations to add substances to the National List. AMS recognizes that a petition submission does not guarantee a favorable outcome for the petitioner, but the process provides ample opportunity for stakeholders to inform the NOSB and the public of the reasons to support a National List exemption. AMS does not have data to more accurately estimate the potential costs of this action on the organic infant formula market and seeks public comments to refine the estimated impact.

Baby Food. The OTA 2011 Organic Industry Survey states that sales of organic baby food totaled \$296 million in 2010. Organic baby food represents a small, but growing share of the baby food market. According to ERS data, sales of organic baby food accounted for approximately 12.2% of the supermarket sales of all baby food in the first quarter of 2009.²⁹ The NOP has observed a range of organic baby food products in various forms, including canned, dry

²⁹ ERS determined the market share for organic baby food by using data from Nielsen Scantrack, which contains weekly sales information from a sample of over 14,000 U.S. grocery stores.

and frozen and has observed the addition of DHA algal oil, choline bitartrate and unidentified sources of DHA and ARA to a few organic baby food products. Within each type, there are organic baby food products which would comply with this proposed action with respect to the addition of vitamins and minerals.³⁰ However, AMS does not have data to determine the proportion of baby food which would be affected by this proposed action and seeks comments to refine this estimate.

AMS believes that the two year implementation phase would minimize any disruption to the organic baby food industry. During this time, the impacted stakeholders have the opportunity to submit petitions to add substances to the National List that would be excluded from use in organic products. The implementation period also provides affected entities with time to consider reformulating products to comply with the proposed action.

Fluid Milk and Dairy Products. The total sales of organic milk and cream sales for 2010 was reported to be \$2.1 billion.³¹ ERS has calculated that 2.8 percent of the universal product codes (UPCs) for organic milk are codes for milk products which contain DHA.³² However, due to variability in the retail price and sales volume for different types of organic milk products, the percentage of UPCs cannot be extrapolated to the percentage of sales that would be affected by this proposed action. AMS does not have data to quantify the percent of organic milk sales that are attributed to milk with DHA and ARA. However, even assuming that the \$2.1 billion in sales

³⁰ For the purpose of labeling, the amount/levels of essential vitamins and minerals in 21 CFR 101.9(c)(8)(iv) are for 4 years and above. Foods that are represented for use for infants (up to 12 months of age), children 1 to 4 years of age, pregnant or lactating women, must use the Recommended Daily Intakes that are specified for the intended group.

³¹ This estimate does not include potential impacts to organic yogurt. The NOP believes such impact would be minimal as there appears to be very few organic yogurt products on the market which contain DHA algal oil. Organic yogurt which contains DHA derived from fish oil is available; this is acceptable for use in organic production currently and under this proposed action.

³² ERS determined this estimate by utilizing data from the Gladson UPC (Universal Product Code) database which contains 160,000 food UPC codes and detailed nutritional information. The 2.8% estimate is based on 2010 data. ERS searched that database for organic milk products containing one or more of the 11 nutrients specified by the NOP: docosaheaxaenoic acid (DHA), arachidonic acid (ARA), taurine, inositol, choline, ascorbyl palmitate, beta-carotene, carnitine, lycopene, nucleotides, and lutein.

could be the upper limit cost of this proposed action, AMS believes that this significantly over estimates the impact of this proposed rule. As indicated by the organic milk UPC data from ERS, the organic fluid milk market includes many products which do not contain added DHA. In addition, not all organic milk products are available in a version containing added DHA. AMS is aware that retail prices for organic milk with added DHA are typically higher than prices for organic milk without added DHA.³³ However, we lack numerical data to describe the economic impact of DHA in the organic milk market, particularly in comparison to other growth drivers such as a narrowing gap between organic and nonorganic milk prices.³⁴ AMS seeks public comments to refine the estimated impact of this proposed action upon organic fluid milk and dairy products.

AMS believes there are additional factors that would mitigate the projected \$2.1 billion impact on the organic dairy sector. One factor is the existence of an alternative form of DHA, derived from fish oil, which is acceptable for use in organic milk and dairy products. Section 205.606 of the National List provides for the use of two components of fish oil, specifically, the omega-3 fatty acids, DHA and eicosapentaenoic (EPA). This estimated cost to the organic dairy sector does not include organic milk which contains DHA from fish oil because the addition of those substances would not be prohibited by this proposed action. While AMS is aware that DHA algal oil has a unique market appeal as a vegetarian source of DHA, there is an allowed source of omega-3 fatty acids to enable operations affected by proposed action to maintain a stake in the niche market for omega-3 organic milk.

³³ NOP analysis of milk prices revealed that organic whole milk with added DHA generally ranged from 30 to 80 cents higher than prices for organic whole milk.

³⁴ The Organic Trade Association 2011 Organic Industry Survey attributes the strong growth of the organic milk/cream category in 2010, to a narrower price gap between organic and nonorganic milk as a result of higher conventional commodity prices.

AMS' estimate assumes that all sales attributed to organic milk with DHA could be potentially affected in the organic milk sector. However, the NOP believes, but does not have affirmative data that some portion of DHA organic milk purchases would transfer to other organic milk products without algal DHA, mitigating the potential loss of organic milk sales to the organic dairy sector. Further, AMS expects that some portion of consumers is chiefly motivated by the perceived benefits of organic certification and would keep their purchases within the organic dairy sector. Such consumer behavior would decrease the estimated sales impact of this proposed action.

In addition, AMS is proposing a two year implementation period. As of the publication of this proposed rule, petitions have been submitted to the NOSB for the addition of DHA algal oil and ARA single-cell oil. During the implementation period, affected entities will have the opportunity to present their public comments to the NOSB regarding DHA algal oil and ARA single-cell oil. If the NOSB approves a recommendation to add these substances to the National List, the length of the implementation period is expected to be adequate to cover the necessary rulemaking and minimize disruption to the industry.

Breakfast Cereal. The sales for organic breakfast cereal totaled approximately \$1 billion in 2010.³⁵ ERS has calculated that 2.8 percent of the UPCs for organic breakfast cereals are codes for cereals which contain a substance that would be prohibited from use in organic products as a result of this proposed rule.³⁶ AMS lacks data on market share of breakfast cereals with any of the identified substances (referred to “added nutrients” for the remainder of this section). While assuming an upper limit of \$1 billion for the estimated impact of this proposed

³⁵ Organic Trade Association, 2011. The 2011 Organic Industry Survey reported \$1.049 billion in sales of “dry breakfast goods” for 2010.

³⁶ ERS determined this estimate by utilizing data from the Gladson UPC (Universal Product Code) database which contains 160,000 food UPC codes and detailed nutritional information. The 2.8% estimate is based on 2010 data. See footnote 19 for a list of the substances included in the search criteria.

action on organic breakfast cereal, the agency considers that this figure is significantly inflated. As evidenced by the ERS data, not all organic breakfast cereals contain an added nutrient(s) that would be affected by this proposed action.

AMS' estimate assumes that all sales attributed to organic breakfast cereal with added nutrients would potentially be affected in the organic breads and grains sector. However, the NOP believes, but does not have affirmative data, that some portion of these purchases would transfer to other organic breakfast cereals, mitigating any potential adverse impact. Further, AMS believes it is accurate to infer that some portion of purchases are motivated by perceived benefits of the organic certification rather than the nutrients added, which would decrease the estimated sales impact.

In addition, the proposed two year implementation period is expected to be sufficient for NOSB consideration of petitions for added nutrients received as of publication of this rule and any rulemaking necessitated by NOSB recommendations on these petitions. As AMS does not have data to more accurately estimate the potential costs of this action on the organic breakfast cereal market, the agency is seeking public comments to refine the estimated impact.

Pet Food. AMS estimates that the potential impact of this proposed action on the organic pet food industry to be \$42 million. According to a Sundale Research report, the 2010 sales for organic pet food totaled \$116 million, 36 percent of which was attributed to sales of cat food.³⁷ The estimated impact of \$42 million is equivalent to the 2010 sales of organic cat food. AMS anticipates that all organic cat food would be impacted by this proposed action because cat food must contain the substance taurine. Taurine is an organic acid which is essential for healthy heart function and prevention of blindness in cats. The amount of taurine must meet the minimal

³⁷ Sundale Research, 2011. *State of the Industry: Natural and Organic Pet Food in the U.S., 4th Edition*, Bayshore, N.Y.

requirement as established for cats by the National Research Council's *Nutrient Requirements of Cats and Dogs* (2006).³⁸ The National List does not contain a specific exemption for the use of taurine, nor does the FDA fortification policy provide for the use of this substance because the policy does not pertain to pet foods.

The \$42 million in sales of organic cat food includes sales of cat treats. According to the Sundale Research data, sales of cat food treats accounted for 12.5 percent of 2010 sales, or \$5.25 million. Pet treats, however, are exempt from including a nutritional adequacy statement and cat treats are not required to include taurine. Therefore, AMS expects that some portion of organic cat treats would not be affected by this proposed action. AMS does not have data on the percent of cat treats that do or do not contain taurine to further refine this estimate. Therefore, the estimate is based on an underlying assumption that all cat treats contain taurine.³⁹ Because AMS does not have data to more accurately estimate the potential costs for organic pet food, the agency is seeking public comments to refine the estimated impact.

AMS intends to address the overall use of nutrient vitamins and minerals in pet food through a separate rulemaking that would establish standards for organic pet food. A petition to add taurine to the National List for use in pet food was submitted to the NOP in September 2010. AMS believes that the NOSB review of the petition and the promulgation of organic pet food regulations will conclude within the implementation phase of this proposed action to mitigate disruption to the organic pet food industry.

In summary, AMS expects that potential impacts on sales of organic products in the aforementioned categories could be mitigated through several factors. The proposed two year

³⁸ The FDA considers the nutrients listed in Tables 15-10, 15-12 and 15-14 to be essential nutrients for cats where a Minimal Requirement or Adequate Intake value has been established in order for the product to be labeled, "complete and balanced."

³⁹ Although taurine is not a required nutrient for dog food, some organic dog foods may contain taurine. However, AMS believes the amount of organic dog food products affected would be minimal.

implementation period is intended to provide time for NOSB to consider petitions for substances that are affected by this action and for AMS to conclude rulemaking to add substances to the National List. The implementation phase would also provide affected entities time to explore reformulation or relabeling of affected products. AMS is seeking comments on the length of the proposed compliance date. Further, AMS believes that if some products are discontinued as a result of this proposed rule, some consumers will purchase, as an alternative, an organic product within the same category rather than a nonorganic product.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such

additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 - 392), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 - 1367).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601- 612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to

certify a rule, in lieu of preparing an analysis if the rulemaking is not expected to have a significant impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this proposed action on small entities. Small entities include producers engaged in crop and animal production and handlers that process organic products or develop, market and sell organic products. AMS has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

AMS notes that several requirements to complete the RFA overlap with the Regulatory Impact Analysis (RIA) and the Paperwork Reduction Act (PRA). For example, the RFA requires a description of the reasons why action by the agency is being considered and an analysis of the proposed rule's costs to small entities. The RIA describes the need for this proposed rule and provides an analysis of the benefits and costs of a proposed rule. Further, the RFA requires a description of the projected reporting and recordkeeping requirements of the proposed rule. The PRA provides an estimate of the reporting and recordkeeping (information collection) requirements of a proposed rule. In order to avoid duplication, we combine some analyses as allowed in section 605(b) of the RFA. The RIA also provides summary information on the size of the organic industry, production capacity and sales by category of organic products with a focus upon those products likely to be affected by this rulemaking. It also provides information on potential costs to handlers that have chosen to obtain organic certification. The RIA and PRA should be referred to for more detail.

This proposed rule would affect handlers involved in manufacturing and/or marketing certain types of organic processed products including, infant formula, baby food, fluid milk, breakfast cereal and pet food. Organic handlers engage in the selling, processing and/or packaging of agricultural products. Some handlers have processing facilities, while others develop formulations and labels and market products, but contract with a co-packer for the manufacturing. For the purposes of this analysis, AMS considered co-packers and marketing operations to be a single handling entity due to the inter-dependent relationship for producing organic products. The Small Business Administration (SBA) (13 CFR 121.201), defines small food manufacturers by the number of employees. SBA identifies various subsectors of the food manufacturing industry by the North American Industry Classification System (Subsector 311 – Food Manufacturing). Entities which manufacture the organic products listed above, with the exception of breakfast cereal, would qualify as a small business if the number of employees does not exceed 500. The small business threshold for breakfast cereal manufacturing is a maximum of 1,000 employees.⁴⁰

Based on USDA data, the total acreage of certified organic land grew from 1.8 million acres in 2000 to 4.8 million acres in 2008, of which approximately 2.2 million acres was pasture and rangeland.⁴¹ The number of certified organic producers in the U.S. nearly doubled in that

⁴⁰ AMS determined that the following North American Industry Classification System categories, from among those listed in the SBA regulations, are relevant to the manufacturing activity that could be affected by this proposed rulemaking: Dry, condensed and evaporated dairy product manufacturing (organic infant formula); Miscellaneous food manufacturing (organic baby food); Fluid milk manufacturing, Breakfast cereal manufacturing, Dog and cat food manufacturing.

⁴¹ U.S. Department of Agriculture, Economic Research Service. 2008. *U.S. Organic Agriculture, 1992-2008*, data set available at www.ers.usda.gov/data/organicERS

time period rising from approximately seven thousand in 2000 to nearly 13,000 in 2008.⁴² ERS estimated the number of certified handling operations was 3,225 in 2007.⁴³

Legal Basis and Objective of Proposal

In 1990, Congress enacted the Organic Foods Production Act of 1990, as amended (OFPA) (7 U.S.C. 6501 - 6522). The OFPA requires all agricultural products labeled as “organically produced” to originate from farms or handling operations certified by a State or private agency that has been accredited by USDA. The OFPA authorizes the Secretary of Agriculture to establish a National List of approved and prohibited substances that meet criteria enumerated in the Act. The exemptions for the use of synthetic substances must be based on proposed amendments of the National Organic Standards Board.

This proposed rule would correct the National List exemption for nutrient vitamins and minerals by replacing the reference to FDA’s fortification policy (21 CFR 104.20) with references to the FDA regulatory provisions that clearly convey what substances are permitted for fortification of food (21 CFR 101.9). This proposed action would also add references for the FDA regulations for the required vitamins and minerals for infant formula (21 CFR 107.100 and 107.10) because the fortification policy does not address the addition of nutrients to infant formula.

Applicability of Proposal

The population that would be directly impacted by this proposed rule is a subset of certified organic handlers of infant formula, baby food, milk, breakfast cereal and pet food. While we do not have precise data, AMS expects the number of organic handlers that could be affected by this proposed action to be substantially less than the entire population of organic

⁴² Ibid.

⁴³ U.S. Department of Agriculture, Economic Research Service, 2009. Data Sets: Procurement and Contracting by Organic Handlers: Documentation available at <http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm>.

handlers which ERS estimated to be 3,225 in 2007. In general, AMS has ascertained that the use of substances that could no longer be added to organic products as a result of this proposed action tends to be concentrated among certain national brands. AMS believes that few of these handlers would be considered small entities under the criteria established by the SBA, as discussed below. AMS is seeking comments on the adequacy of the estimated impact of the proposed action on small entities.

Costs of Proposed Rule - Direct Costs to Handlers

Infant Formula. The Organic Trade Association reported that sales of organic infant formula were \$689 million for the year 2010.⁴⁴ According to measurements by ERS, as of the first quarter in 2009, 99.5 percent of organic infant formula contained added DHA and ARA.⁴⁵ AMS believes that approximately five brands of organic infant formula produced by two manufacturers dominate the U.S. organic infant formula market. Organic infant formula sold under five of these brands contains ingredients, such as, DHA algal oil, ARA single-cell oil, taurine and inositol, which would not be permitted by this proposed action. AMS is confident that two of these entities would not be considered a small business under the SBA criteria.

Baby Food. The Organic Trade Association disclosed that sales of organic baby food totaled \$296 million in 2010.⁴⁶ According to ERS data, sales of organic baby food accounted for approximately 12.2 percent of the supermarket sales of all baby food in the first quarter of 2009.⁴⁷ The baby food category includes products in a variety of forms and ingredients for different age groups ranging from cereals, pureed fruits, vegetables, grains and proteins, snacks

⁴⁴ Organic Trade Association, 2011. *2011 Organic Industry Survey*. Brattleboro, VT.

⁴⁵ ERS determined this number from Nielsen Scantrack data which contains weekly sales information from a sample of over 14,000 U.S. grocery stores.

⁴⁶ Organic Trade Association, 2011. *2011 Organic Industry Survey*.

⁴⁷ ERS determined the market share for organic baby food by using Nielsen Scantrack data, which contains weekly sales information from a sample of over 14,000 U.S. grocery stores.

and yogurt. According to the database of NOP certified operations, the number of U.S. operations handling organic baby food is less than 20.

AMS has observed DHA algal oil, choline bitartrate and unidentified sources of DHA and ARA as ingredients in a few organic baby food products. These ingredients would not be permitted in organic formula by this proposed action unless and until there are specific exemptions on the National List for these substances. In general, however, prevalent use of substances that would be prohibited as a result of this proposed action in organic baby food has not been detected. AMS believes that approximately three entities, which distribute products nationally, would be impacted by this proposed rule. AMS is confident that one of these entities would not meet the criteria for a small business. Based upon the extent of the distribution of products and the marketing channels, AMS is uncertain whether either of the two other entities would qualify as a small business. The products that would be affected by this proposed rule, however, represent only a portion of the organic baby food offerings of these entities. Therefore, AMS believes the impact of this rule, if any, on small entities in the organic baby food category would be negligible. AMS welcomes comments to further inform its determination.

Fluid Milk. The total sales of organic milk and cream for the year 2010 were reported to be \$2.1 billion.⁴⁸ ERS has calculated that 2.8 percent of the universal product codes for organic milk are codes for milk products which contain DHA.⁴⁹ According to ERS, as of May 2007, two

⁴⁸ Organic Trade Association, 2011. *2011 Organic Industry Survey*. This estimate does not include potential impacts to organic yogurt. The NOP believes such impact would be minimal as there appears to be very few organic yogurt products on the market which contain DHA algal oil or other substances that would not be allowed per this proposed action. Organic yogurt which contains DHA or omega-3 fatty acids derived from fish oil is available; this is acceptable for use in organic production currently and would continue to remain compliant under this proposed action.

⁴⁹ ERS determined this estimate by utilizing data from the Gladson UPC (Universal Product Code) database which contains 160,000 food UPC codes and detailed nutritional information. The 2.8% estimate is based on 2010 data. ERS searched that database for organic milk products containing one or more of the 11 nutrients specified by the NOP: docosaheaxaenoic acid (DHA), arachidonic acid (ARA), taurine, inositol, choline, ascorbyl palmitate, beta-carotene, carnitine, lycopene, nucleotides, and lutein.

suppliers were providing about 75 percent of the nationally branded organic milk.⁵⁰ That balance has likely shifted due to the growth in private label brands, many of which are supplied by one organic milk handler. Based on ERS analysis, AMS believes that three organic dairy handlers supply most of the organic milk in the U.S. market (two supplying national brands and one supplying various private label milk). AMS is aware of other organic dairy handlers which distribute on a smaller scale and that the dairy handlers may collect milk from hundreds of organic producers.

One of the national organic milk brands offers several organic milk varieties with added DHA algal oil. There is at least one other organic milk brand which contains DHA algal oil, but which is not distributed on a national scale. Both of these entities would be impacted by the proposed action because DHA algal oil would not be allowed in organic milk unless and until there is a specific exemption on the National List for this substance. AMS believes that one of these companies, which is part of a multinational corporation, would not qualify as a small business as defined by the SBA for fluid milk manufacturing. AMS expects that this action could impact some small milk handlers which offer organic milk with DHA algal oil. However, the Agency concludes that this proposed action would not have a significant impact on these entities as organic milk brands have diversified organic dairy offerings and do not produce or market organic milk with DHA exclusively. The diversification in the product line could help to offset any costs impacts of reformulating or discontinuing some products within a brand. Furthermore, there are alternative sources of DHA from fish oil, which are allowed as ingredients in organic products per section § 205.606 of the National List, and would be

⁵⁰ Dimitri, Carolyn, and Venezia, Kathryn M. *Retail and Consumer Aspects of the Organic Milk Market/LDP-M-155-01*. U.S. Department of Agriculture, Economic Research Service, May 2007.

available to organic handlers that want to remain in or enter the DHA/omega-3 organic milk market niche.

Breakfast cereal. The sales for organic breakfast cereal totaled approximately \$1 billion in 2010.⁵¹ ERS has calculated that 2.8 percent of the universal product codes for organic breakfast cereals are codes for cereals which contain a substance that would be prohibited from use in organic products as a result of this proposed rule.⁵² AMS has not identified which organic cereals, other than those marketed for babies, contain substances which would be prohibited from use in organic products as a result of this proposed action. The projected impacts to organic baby food are described above and in the Regulatory Impact Analysis. AMS believes that this proposed rule would not have a significant impact on a substantial number of small breakfast cereal manufacturers for several reasons. Due to the numerous varieties of organic breakfast cereal on the market, the estimated 2.8 percent of universal product codes which would be impacted by this proposed action represents few products. Organic cereal brands typically offer a variety of cereals, improving the likelihood that not all formulations that would be adversely affected by this proposed action. AMS welcomes comments to further inform our consideration of the impacts of this proposed rule upon the organic breakfast cereal market.

Pet Food. According to a report by Sundale Research, the 2010 sales for organic pet food totaled \$116 million, growing approximately 18 percent over the previous year. AMS believes that this action would adversely impact organic cat food, which accounts for 36 percent of the organic pet food market.⁵³ Organic cat food must contain the substance taurine, an organic acid

⁵¹ Organic Trade Association, 2011. The 2011 Organic Industry Survey reported \$1.049 billion in sales of “dry breakfast goods” for 2010.

⁵² ERS determined this estimate by utilizing data from the Gladson UPC (Universal Product Code) database which contains 160,000 food UPC codes and detailed nutritional information. The 2.8% estimate is based on 2010 data. See footnote 19 for a list of the substances included in the search criteria.

⁵³ Sundale Research, 2011. *State of the Industry: Natural and Organic Pet Food in the U.S., 4th Edition*, Bayshore, N.Y.

which is essential for healthy heart function and prevention of blindness in cats. The amount of taurine must meet the minimal requirement as established for cats by the National Research Council's *Nutrient Requirements of Cats and Dogs* (2006). The National List does not contain a specific exemption for the use of taurine, nor does the FDA fortification policy provide for the use of this substance because the policy does not pertain to pet foods.

AMS has observed that pet food companies which market organic pet foods also offer natural pet food products. AMS is not aware of any pet food companies that exclusively manufacture organic pet foods and believes that the product and market diversification within individual entities to include pet treats, organic dog food and natural pet foods, respectively, provides insulation from the impacts of this proposed action. Furthermore, AMS intends to address the use of nutrient vitamins and minerals in pet food through a separate rulemaking that would establish standards for organic pet food. A petition to add taurine to the National List for use in pet food was submitted to the NOP in September 2010. AMS believes that the NOSB review of any petitions and the promulgation of organic pet food regulations will conclude within the implementation phase of this proposed action to mitigate disruption to the organic pet food industry.

Indirect Costs to Organic Producers

OTA's April 2011 White Paper on the Fortification of Organic Foods includes an estimate of the sales of organic commodities used as ingredients in fortified organic products, which could potentially be impacted by regulatory action to restrict substances used for supplementation in foodstuffs.⁵⁴ OTA calculated the estimated farm gate sales as \$11 million dollars based on a ratio of 1:4:8, for the variables, farm-gate sales, retail sales and total size of the industry, respectively. The OTA White Paper also identifies the range of commodities which

⁵⁴ This is available on the Organic Trade Association website, www.ota.com

supply impacted organic categories. The organic commodity supply stream includes meats and poultry, grains, tree fruit, vegetables, nuts, fluid milk and milk powder, and soy.

Small agricultural producers are defined by the Small Business Administration (SBA) (12 CFR 121.201) as those having receipts of less than \$750,000. The majority of organic ingredient producers whose agricultural products are diverted to organic infant formula, baby food, milk, breakfast cereal and pet food would likely qualify as small agricultural producers. While we do not have precise data, AMS expects the number of producers of organic ingredients that could be affected by this proposed action to be substantially less than the entire population of organic producers which ERS estimated to be nearly 13,000 in 2008. This proposed rule is not expected to have an impact on a substantial number of small agricultural producers. According to ERS, the demand for organic products has historically exceeded the supply of organic ingredients. In 2004, ERS conducted a survey of organic handlers and found that 13% experienced critical shortages for one of their organic products and concluded that 38% were importing raw, organic materials produced outside the U.S.⁵⁵ That discrepancy persists according to the OTA “2011 Organic Industry Survey” which reported difficulty, ranging from major to occasional, with the supply of organic raw materials. This report also indicated that 62 percent of companies surveyed in 2010 intended to increase their use of organic ingredients over the next three years. Given the projections for continued expansion of the organic sector, AMS expects that there will be opportunities for producers to divert organic agricultural products to other purchasers to buffer the impact of any disruption to the manufacture of certain processed organic products as a result of this proposed action.

⁵⁵ Greene, Catherine, Carolyn Dimitri, Biing-Hwan Lin, William McBride, Lydia Oberholtzer, and Travis Smith. *Emerging Issues in the U.S. Organic Industry*. EIB-55. U.S. Dept. of Agriculture, Economic Research Service. June 2009.

Organic meat and poultry producers that supply the organic pet food industry, however, could face more formidable challenges. The organic pet food market facilitates carcass utilization for organic meat and poultry parts which do not enter human food chain. Poultry producers, in particular, would be prone to experience a greater impact because chicken comprises most of the protein in organic pet food. AMS does not know the number of organic poultry producers that supply the organic pet food sector.

Conclusion

This proposed rule would correct the National List exemption for nutrient vitamins and minerals by replacing the reference to FDA's fortification policy (21 CFR 104.20) with references to the FDA regulatory provisions that clearly convey what substances are permitted for fortification of food (21 CFR 101.9). This proposed action would also add references for the FDA regulations for the required vitamins and minerals for infant formula (21 CFR 107.100 and 107.10) because the fortification policy does not address the addition of nutrients to infant formula. Overall, this proposed action would narrow the number of potential substances for addition to organic foods in comparison of NOP's current interpretation of the exemption for nutrient vitamins and minerals. This proposed rule would establish a finite list of essential and required vitamins and minerals for food and infant formula. Sustained consumer demand is essential to the economic stability of organic producers and handlers, and this proposed action would bridge consumer expectations and the innovation of organic operations.

The proposed revisions to the exemption for nutrient vitamins and minerals could entail costs for certified operations which are manufacturing and/or marketing organic products that contain substances which fall outside the revised parameters for nutrient vitamins and minerals. The costs associated with this proposed rule could include reformulating products to remove

nonagricultural ingredients that are clearly prohibited by the National List and relabeling products to reflect formulation changes. The types of substances that would be restricted by this proposed action are nutrients which are not added to have a functional effect on the product, but for nutrient content and may be associated with a nutritional claim. Therefore, the removal of these ingredients from product formulations is not expected to necessitate procurement of substitute ingredients. Due to the diversity of products and ingredients that may be affected by this rule, AMS is not attempting to quantify the range of possible of reformulation and relabeling to individual operations.

AMS believes that this proposed rule would facilitate increased consumer confidence in organic products. This proposed action would clearly delineate the requirements for adding vitamins and minerals to organic foods and infant formula, and foster the consistent implementation and enforcement of these requirements. Furthermore, this proposed action does not preclude the potential for substances excluded from use to be considered for future use in organic products, but it would require that use be predicated upon the review and recommendation of the NOSB. That process will ultimately bolster the certainty of organic handlers about the regulatory status of ingredients, deter consumer skepticism and improve the competitiveness of the market for organic foods.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35, or OMB's implementing regulation at 5 CFR part 1320.

AMS is committed to complying with the E-Government Act to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

E. Civil Rights Impact Analysis

AMS has reviewed this proposed rule in accordance with the Department Regulation 4300-4, Civil Rights Impact Analysis (CRIA), to address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, AMS has determined that this rule would only impact the organic practices of handlers and that this rule has no potential for affecting handlers in protected groups differently than the general population of handlers. This rulemaking was initiated to clarify a regulatory requirement and enable consistent implementation and enforcement.

Protected individuals have the same opportunity to participate in the NOP as non-protected individuals. The NOP regulations prohibit discrimination by certifying agents. Specifically, § 205.501(d) of the current regulations for accreditation of certifying agents provides that "No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status." Paragraph 205.501(a)(2) requires "certifying agents to demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart" including the prohibition on discrimination. The granting of accreditation to certifying agents under § 205.506 requires the review of information submitted by the certifying agent and an on-site review of the certifying agent's operation. Further, if certification is denied, § 205.405(d) requires that the certifying agent notify the

applicant of their right to file an appeal to the AMS Administrator in accordance with § 205.681. These regulations provide protections against discrimination, thereby permitting all handlers, regardless of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status, who voluntarily choose to adhere to the proposed rule and qualify, to be certified as meeting NOP requirements by an accredited certifying agent. This proposed rule in no way changes any of these protections against discrimination.

List of Subjects in 7 CFR Part 205.

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, is proposed to be amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

2. Section 205.605(b) is amended by:

A. Removing the listing for “Nutrient vitamins and minerals”.

B. Adding a listing for “Vitamins and minerals”.

The addition reads as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”

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(b) * * *

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Vitamins and minerals. For food—vitamins and minerals identified as essential in 21 CFR § 101.9. For infant formula—vitamins and minerals as required by 21 CFR § 107.100 or § 107.10.

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